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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,360	02/17/2004	Matti Huiku	2532-00342	9931
26753	7590	06/14/2006	EXAMINER	
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,360

Applicant(s)

HUIKU, MATTI

Examiner

Karen E. Toth

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 11-12, 17-18, 20, 23 is/are rejected.
- 7) ☒ Claim(s) 2, 7-10, 13-16, 19, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/04, 5/18/05, 7/28/05</u> <i>WT</i> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-23, drawn to a method and apparatus for neurological monitoring.
- II. Claims 24-29, drawn to a sensor for obtaining a biosignal.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Invention II may be used to obtain data from a location other than the cortex or subcortex of a patient, as specified in Invention I; Invention I may obtain biosignal data from a sensor that does not comprise a flexible substrate, as specified in Invention II.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their

Art Unit: 3735

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Daniel Fetterly on 4 May 2006 a provisional election was made with traverse to prosecute the invention of Invention I, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3735

7. The examiner notes that the applicant has defined subcortex-related activity to include activity from the brainstem, spinal cord, and peripheral nervous system of the patient (page 5, lines 15-16).

8. Claims 1, 3, 4, 5, 18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gevins'166 (US Patent 5447166).

Regarding Claim 1, Gevins'166 discloses a neurological monitoring method comprising obtaining cortex-related biosignal data (column 6, lines 42-47); obtaining subcortex-related biosignal data, including impedance signal data (column 6, lines 48-52); calculating a cortical activity indicator and a sub-cortical activity indicator (column 5, lines 33-35); and calculating an overall indicator from the previous indicators (column 5, lines 38-43; column 9, lines 11-15).

Regarding Claim 3, Gevins'166 further discloses that the sub-cortical activity data collection and analysis may include ECG signal data (column 6, lines 50-51; column column 7, lines 10-13).

Regarding Claims 4 and 5, Gevins'166 further discloses that the sub-cortical activity data collection and analysis may include EMG signal data (column 6, line 51; column 7, lines 7-10).

Regarding Claim 14, the steps of obtaining cortex- and subcortex-related biosignal data may be performed simultaneously.

Regarding Claim 18, Gevins'166 discloses an apparatus comprising means for obtaining cortex-related biosignal data (column 6, lines 42-47); means for obtaining subcortex-related biosignal data, including impedance signal data

Art Unit: 3735

(column 6, lines 48-52); means for calculating a cortical activity indicator and a sub-cortical activity indicator (column 5, lines 33-35); and means for calculating an overall indicator from the previous indicators (column 5, lines 38-43; column 9, lines 11-15).

Regarding Claim 20, Gevins'166 further discloses that signal data such as ECG and EMG data may be collected (column 6, lines 50-51; column 7, lines 7-13).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gevins'166 in view of Barsa'640 (US Patent 4570640).

Regarding Claim 6, Gevins'166 discloses all the elements of the current invention, as applied to claims 1, 2-5, 18, and 20 above, except for obtaining a measure of the rate at which changes occur in the bioimpedance signal data.

Barsa'640 teaches a method of neurological monitoring comprising measuring the rate of changes in bioimpedance signal data (column 15, lines 36-38), in order to better test the patient's sympathetic integrity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Gevins'166 in view of Barsa'640 and included measuring the rate of changes in the bioimpedance signal data, as taught by Barsa'640, in order to better test the patient's sympathetic integrity.

Regarding Claim 12, Gevins'166 in view of Barsa'640 discloses all the elements of the current invention, except for obtaining a measure of the power spectrum of the EMG.

Barsa'640 further teaches that the EMG data to be analyzed is the power spectrum of the data (column 23, lines 60-61), so that the patient's status with respect to consciousness can be accurately estimated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Gevins'166 in view of Barsa'640, and analyzed the power spectrum of the EMG data, as taught by Barsa'640, so that the patient's status with respect to consciousness can be accurately estimated.

Art Unit: 3735

11. Claims 11, 17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gevins'166 in view of John'444 (US Patent 6016444).

Regarding Claim 11, Gevins'166 discloses all the elements of the current invention, as applied to claims 1, 2-5, 18, and 20 above, except for the cortex-related data including EEG data, and the analysis including a measure of the EEG's entropy.

John'444 teaches a method of monitoring the neurological state of patient, comprising obtaining cortex-related data in the form of EEG data (column 3, lines 31-42), and using the variance of the EEG signals for analysis (column 10, lines 13-17), in order to obtain a more accurate representation of the patient's status.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Gevins'166, and included EEG data in the collected cortex-related data, and analyzed the EEG's entropy, as taught by John'444, in order to obtain a more accurate representation of the patient's status.

Regarding Claim 17, Gevins'166 discloses all the elements of the current invention, as applied to claims 1, 2-5, 18, and 20 above, except for the indicators being supplied as input data to a device for administering drugs.

John'444 further discloses producing indicators, including an indicator based upon the cortex-related activity (column 10, lines 39-51), and using the indicators as inputs for a device for administering drugs to a patient (column 1, lines 6-9), in order to accurately control the patient's state.

Art Unit: 3735

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Gevins'166 with the additional step of using the indicators to control a device for administering drugs to a patient, as taught by John'444, in order to accurately control the patient's state.

Regarding Claim 23, Gevins'166 discloses all the elements of the current invention, as applied to claims 1, 2-5, 18, and 20 above, except for the means for analyzing the biosignal data being connected to a device configured to administer drugs to a patient.

John'444 discloses a neurological monitoring apparatus comprising a device for administering drugs to a patient (column 1, lines 6-9), in order to accurately control a patient's state.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gevins'166 with a device for administering drugs to a patient, as taught by John'444, in order to accurately control the patient's state.

Allowable Subject Matter

12. Claims 2, 7-10, 13-16, 19, 21, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of Claim 2, including, *inter-alia*, calculating only a bioimpedance signal indicator when calculating subcortical indicators.

Art Unit: 3735

The prior art of record fails to anticipate or make obvious the method of Claims 7-10, including, *inter-alia*, deriving bioimpedance signal data in order to determine changes in the data and determine the rate at which the data exceeds a predetermined threshold.

The prior art of record fails to anticipate or make obvious the method of Claims 13-16, including, *inter-alia*, using at least one common electrode to obtain both cortex- and subcortex-related data.

The prior art of record fails to anticipate or make obvious the structure of Claim 19, including, *inter-alia*, means for obtaining only bioimpedance data when gathering subcortical signals.

The prior art of record fails to anticipate or make obvious the structure of Claims 21-22, including, *inter-alia*, at least one common electrode that may be used to obtain both cortex- and subcortex-related data.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 3468302 to Cowell, which discloses an apparatus and method for measuring skin resistance.

US Patent 4697599 to Woodley, which discloses a method and apparatus for measuring subcortex-related data.

US Patent 6571124 to Storm, which discloses a method and apparatus for measuring subcortex-related data.

Art Unit: 3735

US Patent Application Publication 2004/0243017 to Causevic, which discloses a method and apparatus for measuring cortex-related data.

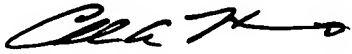
US Patent Application Publication 2005/0059899 to Merilainen, which discloses a method and apparatus for measuring cortex-related data.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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